

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

SHAFIGHEH KOUBLANI,

Plaintiff,

-vs-

: 2:20-cv-01741-DRH-AYS

COCHLEAR LIMITED AND COCHLEAR
AMERICAS,

: **Oral Argument
Requested**

Defendants.

:
x

**DEFENDANT COCHLEAR AMERICAS CORPORATION'S
MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS**

Lauren S. Colton (*pro hac vice*)
HOGAN LOVELLS US LLP
100 International Drive, Suite 2000
Baltimore, MD 21202
Tel.: (410) 659-2700
Fax: (410) 659-2701
Lauren.colton@hoganlovells.com

David J. Baron
HOGAN LOVELLS US LLP
390 Madison Avenue
New York, New York 10017
Tel: (212) 918-3000
Fax: (212) 918-3100
david.baron@hoganlovells.com

*Attorneys for Defendant Cochlear Americas
Corporation*

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Defendant Cochlear Americas Corporation (“CAM”) submits this Memorandum of Law in Support of its Motion to Dismiss the Amended Complaint (ECF No. 18) (“Compl.”) pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

This product liability action concerns a Nucleus CI522 cochlear implant device (the “CI522 Device”), a state-of-the-art medical device that was approved by the United States Food and Drug Administration (the “FDA”) pursuant to that agency’s rigorous premarket approval (“PMA”) process and distributed in the United States by Defendant Cochlear Americas Corporation (“CAM”). The CI522 Device electrically stimulates nerves inside the ear through an implanted electrode, thereby restoring a sense of hearing to those with severe to profound nerve deafness. Because the implanted component of the CI522 Device includes a magnet, recipients and their healthcare providers need to take certain precautions before undergoing MRI procedures to reduce the risk of the magnet becoming dislodged. For this reason, on July 8, 2016, the FDA approved a supplement to the CI522 Device’s PMA to allow the distribution of a Bandage and Splint Kit for MRI (the “MRI Kit”) to stabilize the magnet during certain MRI procedures. Turning a blind eye to the regulatory history of the device and controlling law, Plaintiff improperly seeks to pursue state law claims attacking the FDA-approved use of the subject medical device.

Plaintiff’s Complaint, based on conclusory allegations that she was injured as a result of some unidentified defect in the MRI Kit when her CI522 Device’s implant magnet became dislodged during an MRI procedure, fails for two reasons. *First*, because the CI522 Device and the MRI Kit were approved pursuant to the FDA’s rigorous PMA process, all of Plaintiff’s claims are expressly preempted by federal law, and United States Supreme Court precedent and the law in this Circuit clearly mandate dismissal. *Second*, even if her claims were not preempted,

Plaintiff has not pled – and cannot plead – any viable claims against CAM under New York law. She does not and cannot plead the existence of any specific design or manufacturing defect or failure to warn affecting the MRI Kit to support a strict liability claim. She does not and cannot plead a duty owed by CAM or an act or omission in violation of that duty to give rise to a negligence claim. And, she does not and cannot plausibly plead any express warranty (beyond generic representations consistent with the CI522 Device’s FDA-approved indication) made to her regarding the MRI Kit or that she relied on any such warranty, nor does she plead any facts – beyond boilerplate allegations – to support a claim for breach of any implied warranty. The Complaint should be dismissed in its entirety.

BACKGROUND¹

A. The Parties

Defendant Cochlear Limited (“CLTD”) is a foreign corporation with its principal place of business located in New South Wales, Australia. (Compl. ¶ 3).² It manufactures cochlear implant devices that bring a sensation of hearing to those who are deaf or suffer a severe hearing impairment. (*Id.* at ¶ 19). CLTD has not been served with process or appeared in this case.

¹ CAM disputes many of Plaintiff’s factual contentions, but acknowledges that, solely for purposes of deciding CAM’s motion to dismiss, the Court must accept as true all well-pled allegations of fact contained in the Complaint. The Court need not, however, accept as true “conclusory allegations or legal conclusions masquerading as factual conclusions,” or factual claims that are contradicted by documentary evidence relied upon in the Complaint. *Smith v. Local 819 I.B.T. Pension Plan*, 291 F.3d 236, 240 (2d Cir. 2002) (internal quotation omitted); *see also Tufamerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013) (“If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control[s], and the court need not accept the allegations in the complaint as true.”) (internal quotation omitted). Additionally, the Court may take judicial notice of facts found in documents publicly available on the FDA’s website relating to the CI522 Device and the MRI Kit. *See, e.g., Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 134 n.4 (E.D.N.Y. 2018) (“District courts may take judicial notice of public records of the FDA on a motion to dismiss.”); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (taking judicial notice of FDA documents relating to approved medical device).

² Although Plaintiff does not specify in the Complaint, CLTD is an Australian public company.

Defendant CAM, a separate legal entity formed as a subsidiary of CLTD, distributes CLTD products in the United States. (*Id.* at 9-11).³

Plaintiff Shafiqeh Koublani, a New York resident, was surgically implanted with a CI522 Device manufactured by CLTD on or about March 14, 2017. (*Id.* at ¶ 18). On or about February 14, 2018, Plaintiff underwent an MRI procedure, and an MRI Kit manufactured by CLTD allegedly was applied to Plaintiff by medical staff during the course of that procedure. (*Id.* at ¶¶ 23, 26-27, 30-31).

B. The CI522 Device and the MRI Kit

The CI522 Device is a state-of-the-art surgically implanted electronic device that restores a level of auditory sensation to recipients who are profoundly deaf or severely hearing impaired. (Compl. ¶ 9).⁴ The device, which incorporates both an external component and an implanted internal component, works by electronically stimulating nerves inside the inner ear. The external component of the device consists of a microphone, sound processor and transmitter system. The implanted component consists of a receiver and electrode system, which contains the electronic circuits that receive signals from the external system and send electrical currents to the inner ear. The internal component also includes a magnet, which holds the external component in place next to the internal implanted system. Cochlear implants receive sound from the outside environment, process that sound, and then send small electric currents to an area near the auditory nerve. These electric currents activate the nerve, which sends a signal that the brain

³ Plaintiff incorrectly alleges that “Defendants” manufactured and designed the CI522 Device and the MRI Kit. (*See, e.g.*, Compl. at ¶¶ 13, 18, 53-57). As a mere distributor of CLTD products, however, CAM had no role in the design or manufacture of the CI522 Device or the MRI Kit. Of course, solely for purposes of this motion, CAM necessarily accepts the factual allegations of the Complaint as true.

⁴ A full description of CLTD’s implants is found on the FDA’s website at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/CochlearImplants/default.htm>.

learns to recognize as “hearing.” Cochlear devices have been commercially available in this country since the mid-1980s, when they first were approved for use by the FDA.

Because the internal component of the CI522 Device includes a magnet, patients and their healthcare providers must take special precautions before undergoing certain medical procedures, including MRI procedures.⁵ MRIs subject patients to magnetic fields, which can interact with the implant magnet and, in some cases, dislodge the magnet or the implant itself. For this reason, CLTD designed the CI522 Device so that the magnet could be surgically removed by the patient’s healthcare provider prior to undergoing an MRI procedure if desired. Specifically, the magnet can be removed from the top of the implant by making a small incision, without having to move, lift or excessively manipulate the implant itself. Common clinical practice is to remove the magnet before a patient’s MRI procedure. The CI522 is FDA-approved to allow the MRI of implant recipients up to and including 3.0 Tesla after the magnet is surgically removed. (*See Exhibit A*).⁶

To provide a less invasive option to patients and their healthcare providers, in 2016 Cochlear obtained FDA approval for the Nucleus Implant Bandage and Splint Kit for MRI (the “MRI Kit”) which, if properly applied, reduces the likelihood of magnet or implant dislodgment while undergoing an MRI up to 1.5 Tesla without surgically removing the magnet in advance. (*See Compl. ¶ 22; Exhibit A*). The MRI Kit is comprised of a flat plastic splint, which is placed

⁵ A description of the risks and benefits of cochlear implants, including risks relating to MRI procedures such as dislodging the implant, can be found at: <https://www.fda.gov/medical-devices/cochlear-implants/benefits-and-risks-cochlear-implants> (“Even being close to an MRI imaging unit will be dangerous because it may dislodge the implant or demagnetize its internal magnet. FDA has approved some implants, however, for some types of MRI studies done under controlled conditions.”).

⁶ See PMA Supplement P970051, S137 (July 8, 2016), available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S137> (copy attached as Exhibit A). As explained in note 1, *supra*, this Court may refer to matters of public record on the FDA website when ruling on CAM’s Motion to Dismiss.

by a physician, healthcare provider or radiology technician against the skin over the implant magnet site and secured with an elasticized compression bandage and surgical tape. (Compl. ¶ 29).⁷ The provider must carefully locate the magnet site and follow instructions in applying the bandages to ensure that the splint fully covers the magnet site, and that the bandage fully covers the splint.

C. The PMA Approval Process

The CI522 Device and the MRI Kit are medical devices subject to the requirements of the Medical Device Amendments (“MDA”), adopted by Congress in 1976, that “swept back some state obligations and imposed a regime of detailed federal oversight.” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). In enacting the MDA, Congress struck a careful balance between regulation and innovation. Hence, the MDA “provide[s] for the safety and effectiveness of medical device[s],” while simultaneously “encourage[ing] the [] research and development” of “sophisticated, critically important devices.” See Medical Device Amendments, Pub. L. No. 94-295, 90 Stat. 539; S. Rep. No. 94-33, at 2 (1975).

As *Riegel* explains, the MDA divides medical devices into three classes based on the level of risk they pose. *Riegel*, 555 U.S. at 316-17; 21 U.S.C. § 360c(a)(1). Devices that present a potential “unreasonable risk of illness or injury” or that are used to “sustain [] human life or for a use which is of substantial importance in preventing impairment of human health” are classified as Class III devices and receive “the most federal oversight.” *Riegel*, 552 U.S. at 317

⁷ See Cochlear Nucleus Bandage and Splint Kit for MRI (MRI Kit) Instructions, available at: https://www.cochlear.com/0f9a17f2-aa28-4fec-bdad-2f86d2b47627/FUN2706-Cochlear_Nucleus_Implant_Bandage_Splint_Kit_for_MRI.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE-0f9a17f2-aa28-4fec-bdad-2f86d2b47627-lyX0k5Q.

(quoting 21 U.S.C. § 360c(a)(1)(C)(ii)); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (noting that a Class III device “incur[s] the FDA’s strictest regulation”).

All Class III devices must be approved by the FDA before they can be sold on the market. But some Class III devices – including the CI522 Device and the MRI Kit – undergo the “rigorous regime” known as the premarket approval process, or “PMA.” *Riegel*, 552 U.S. at 317-18. The PMA process requires a manufacturer to submit extensive information in an application to the FDA, including, among other things, “full reports of all studies and investigations of the device’s safety and effectiveness that have been published or should reasonably be known to the applicant; a ‘full statement’ of the device’s ‘components, ingredients, and properties and of the principle or principles of operation’; ‘a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device’; samples or device components required by the FDA; and a specimen of the proposed labeling.” *Id.* at 318 (quoting 21 U.S.C. § 360e(c)(1)). The FDA spends an average of 1,200 hours reviewing each voluminous PMA application, and only about 30 Class III devices manage to pass through the rigors of the PMA process each year (in contrast, the FDA approves over 3,000 Class II devices each year). *Id.* at 317-18.

Congress devised the rigorous PMA process because it was important to ensure that manufacturers minimize patient risk and yet continue to innovate. The FDA grants premarket approval only if there is “reasonable assurance” of the device’s safety and effectiveness. *Id.* Thus, whereas traditional state statutory or common law may have imposed a different standard on manufacturers (e.g., strict liability), the FDA “may . . . approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.” *Id.* at 318.

Given the FDA’s regulation of approved Class III medical devices, and given the stated intention of Congress to protect innovations in device technology from being “stifled by unnecessary restrictions,” H.R. Rep. No. 94-853, at 12 (1976), Congress incorporated into the MDA an express preemption clause. *Id.* at 45. Section 360k(a) of the MDA provides that with respect to PMA-approved devices, no state may impose “any requirement” relating to the safety or effectiveness of the device, or any other matter regulated by FDA, that “is different from, or in addition to, any requirement applicable . . . to the device” under federal law. 21 U.S.C. § 360k(a). As the Supreme Court held in *Riegel*, by expressly preempting state claims challenging the design, manufacturing process, or labeling of a premarket-approved medical device, Congress prevented jury second-guessing of an FDA determination that a particular device was safe and effective. *See Riegel*, 552 U.S. at 325-26.

The CI522 Device, including the MRI Kit at issue in this lawsuit, is a Class III device subject to the FDA’s most stringent standards. The CI522 Device was approved as a supplement to PMA P970051, which was originally approved by FDA on June 25, 1998. As any medical device changes and evolves, the manufacturer must supplement its submissions to the FDA per regulation. A manufacturer must submit a “PMA Supplement” for modifications affecting the safety or effectiveness of a Class III device that has already received PMA approval, including for any “new indication for use of the device.” *See* 21 C.F.R. §§ 814.39(a)(1), 814.3(g). The submission requirements applicable to a PMA Supplement are the same as those for an original PMA, although the manufacturer need only provide information necessary to support the proposed modifications. *See* 21 C.F.R. § 814.39(c). Thus, a PMA Supplement imposes “specific federal requirements” for purposes of preemption, just like the original PMA. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 228 (6th Cir. 2000); *see also Riegel*, 552 U.S. at 319, 322.

The PMA Supplement for the CI522 Device was initially approved by the FDA on June 15, 2015 after it was determined that the CI522 Device satisfied the rigorous requirements of the PMA process. (*See Exhibit B*).⁸ A later PMA Supplement provided for a change in indication to allow recipients implanted with a CI522 Device to undergo MRI procedures at 1.5 Tesla using the MRI Kit. The FDA approved that PMA Supplement on July 8, 2016, after determining that the MRI Kit satisfied the rigorous requirements of the PMA process. (*See Exhibit A*).

D. Plaintiff's Alleged Injury and Her Claims

Plaintiff alleges that she underwent an MRI procedure on or about February 14, 2018, and that the MRI Kit was used but did not function as represented by Defendants. (Compl. ¶¶ 23-32). She claims that, as a result, her implant magnet dislodged, requiring revision surgery to explant and re-implant her CI522 Device. (*Id.* at ¶ 38). Plaintiff does not explain how the MRI Kit purportedly failed.⁹ Nor does she specify what “representations” Defendants allegedly made regarding the functionality of the device, except to state in conclusory fashion that “[p]rior to February 14, 2018, Defendants represented to Plaintiff and/or to her physicians that the MRI procedure could be safely performed upon Plaintiff, with the [CI522 Device] in situ, without removal of the Magnet, provided the MRI Kit was first applied to Plaintiff in the manner directed by Defendants” and that “Defendants specifically represented to Plaintiff and/or her physicians that Plaintiff ‘can be safely scanned’ using ‘the MRI Kit for MR scans at 1.5 T[esla] with the

⁸ See PMA Supplement P970051, S126 (June 15, 2015), available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S126> (copy attached as Exhibit B).

⁹ Plaintiff incorrectly alleges that Defendants “issued a recall of the MRI Kit, due to an increase in the number of MRI Kit failures.” (Compl. ¶ 33). Plaintiff’s allegation is refuted by the absence of any entry for the MRI Kit in the FDA’s publicly available database of medical device recalls, *see* <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>, and therefore is not entitled to any presumption of truth. *See supra* note 1. CAM ceased distributing the MRI Kit in the United States as of January 2020, but there has been no “recall” of the MRI Kit.

implant magnet in place.” (Compl. ¶ 24-25). The Complaint does not explain when or how such representations were made or whether or how Plaintiff or her physicians relied on them.

Tellingly, Plaintiff’s allegations in this lawsuit are inconsistent with allegations she asserted in a 2018 medical malpractice lawsuit regarding the same February 14, 2018 MRI procedure. In that lawsuit, she alleged that her treating healthcare providers “negligently and carelessly departed from good and accepted medical practices” and “fail[ed] to treat Plaintiff with the accepted and proper medical management” in connection with the MRI procedure. (*See* Exhibit C, ¶¶ 22-25).¹⁰ She claimed that her healthcare providers negligently performed the MRI, and failed to follow guidelines and manuals in doing so. (*See* Exhibit D, ¶ 3).¹¹ She did not assert any claims or make any allegations of defective equipment in that lawsuit. (*Id.* at ¶ 7).

Notwithstanding the contradictory allegations in her previously-filed medical malpractice lawsuit, Plaintiff asserts four separate causes of action against CLTD and CAM: (1) strict liability, based on defective design and manufacture and failure-to-warn; (2) negligent design and manufacture; (3) breach of express and implied warranty; and (4) negligent failure to warn.¹² Plaintiff seeks compensatory damages for pain and suffering, past and future medical expenses and related out-of-pocket expenses and lost earnings. (Compl. at p. 11).¹³

¹⁰ See Medical Malpractice Complaint, *Koublani v. Doe, et al.*, Index No. 609756/18, Dkt. No. 1 (N.Y. Sup. Ct., Nassau Cnty. (July 23, 2018) (copy attached as Exhibit C).

¹¹ See Medical Malpractice Bill of Particulars, *Koublani v. Doe, et al.*, Index No. 609756/18, Dkt. No. 15 (N.Y. Sup. Ct., Nassau Cnty. Oct. 10, 2018) (copy attached as Exhibit D).

¹² Plaintiff’s original Complaint included claims for strict liability and negligence based on unidentified purported failures with respect to the “implantation” and “testing” of the CI522 Device and/or the MRI Kit, but she has abandoned those claims in her Amended Complaint. (*Compare* ECF No. 1-2 ¶¶ 24-25, 33-34 with Compl. ¶¶ 43-44, 53-57).

¹³ It is unclear what Plaintiff is seeking to recover with respect to medical expenses, given that the costs of her medical treatment relating to her revision surgery were paid by her insurer. (*See* Exhibit D, p. 6, ¶ 3).

LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must “nudge[]” claims “across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570. Further, “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action will not do.’” *Landon v. Wachovia Sec., LLC*, No. 12-cv-3277, 2013 WL 4432383 at *8 (E.D.N.Y. Aug. 12, 2013). A plaintiff must do more than offer “‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). Factual allegations must be enough to raise a right to relief above the speculative level and there must be “more than a sheer possibility that a defendant has acted unlawfully.” *Id.*

ARGUMENT

A. Plaintiff’s Claims Are Expressly Preempted

Section 360k(a) of the MDA provides for the preemption of state requirements “different from, or in addition to” federal requirements relating to the safety or effectiveness of a medical device. 21 U.S.C. § 360k(a). In *Riegel*, the United States Supreme Court confirmed that Section 360k(a) preempts “common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA].” *Riegel*, 552 U.S. at 315; *see also Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 210-12 (E.D.N.Y. 2017) (dismissing product liability claims against Class III device manufacturer as preempted).

Riegel articulated a two-step approach for determining whether the MDA preempts a particular state law claim concerning a medical device. *First*, a court must determine whether the federal government has established requirements applicable to the medical device at issue. *Riegel*, 552 U.S. at 321. Claims involving a device that has received premarket approval, such as the CI522 Device and the MRI Kit at issue here, automatically satisfy the first step. *See Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 279 (E.D.N.Y. 2009). *Second*, the court must determine whether the state-law claim would impose any requirements that “relate to safety and effectiveness” and that are “different from, or in addition to” the federal requirements. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 322-23. Courts in this district recognize that common-law causes of action for negligence, strict liability and breach of warranty, like those asserted here, impose “requirements relating to the safety or effectiveness of the device,” as that term is used in Section 360k(a). *See Babayev*, 228 F. Supp. 3d at 212 (citing *Riegel*, 552 U.S. at 323); *Horowitz*, 613 F. Supp. 2d at 279-80. Because each of her claims depends on a finding that the CI522 Device or the MRI Kit should have been designed, manufactured, tested, marketed and/or labeled in a manner different from that approved by the FDA through the PMA process, all of those claims are preempted. *See Riegel*, 552 U.S. at 329.

There is a narrowly circumscribed exception to preemption under § 360k(a) for claims based on state-law duties that “parallel, rather than add to, federal requirements,” *Riegel*, 552 U.S. at 330 (quotation omitted), but that exception does not apply here. A “parallel” claim must rest on the violation of a state-law requirement that is “identical” to an existing federal requirement, and Plaintiff bears the burden of pleading *specific* PMA requirements that have been violated and specific allegations as to how those violations caused her injury. *See Crissi v.*

Johnson & Johnson Vision Care, Inc., No. 15-CV-4230(ENV)(SMG), 2016 WL 4502038, at *2 & n.2 (E.D.N.Y. Aug. 25, 2016). Plaintiff has failed to do so here.

Courts in this district and elsewhere have not hesitated to dismiss claims against Class III device manufacturers as preempted where, as here, the Complaint does not even attempt to identify a specific PMA requirement or other federal regulation that has been violated. *See, e.g.*, *Crissi*, 2016 WL 4502038, at *2-3; *Tansey v. Cochlear Ltd.*, No. 13-CV-4628 SJF, 2014 WL 4829453, at *9-13 (E.D.N.Y. Sept. 26, 2014) (dismissing strict liability and negligence claims based on design defect and failure to inspect); *Cordova v. Smith & Nephew, Inc.*, No. 14-CV-351 (JFB) (ARL), 2014 WL 3749421, at *6-7 (E.D.N.Y. July 30, 2014) (dismissing design defect and failure to warn claims as preempted for failure to identify the violation of any federal requirement); *Franzese v. St. Jude Med., Inc.*, No. 13-CV-3203(JS)(WDW), 2014 WL 2863087, at *4-8 (E.D.N.Y. June 23, 2014) (dismissing several claims similar to those asserted here as preempted); *Burkett v. Smith & Nephew Gmbh*, No. CV 12-4895(LDW)(ARL), 2014 WL 1315315, at *4-8 (E.D.N.Y. Mar. 31, 2014) (same); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (dismissing a complaint because the “[p]laintiff fail[ed] to set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged”); *Horowitz*, 613 F. Supp. 2d at 280 (“Plaintiff’s generalized allegations cannot withstand preemption because they fail to establish the necessary link between defendants’ federal violations and [plaintiff’s] alleged causes of action.”); *Gale*, 989 F. Supp. 2d at 249(dismissing the complaint where “plaintiff neither provide[d] a factual basis for finding [the defendant] violated federal law, nor allege[d] facts supporting an inference that he was implanted with products designed or manufactured in contravention of the FDA’s premarket approval”); *cf. Babayev*, 228 F. Supp. 3d at 216 (plaintiff failed to state a parallel claim where “the pleading

does not allege plausible facts that even suggest the nature of the defect or adulteration”). This Court should do the same.

1) Plaintiff’s Strict Liability Claims Are Preempted

In her first cause of action, Plaintiff asserts claims for strict liability based on design, manufacturing and warnings defects. (Compl. ¶¶ 43-46); *see also McCarthy v. Olin Corp.*, 119 F.3d 148, 154 (2d Cir. 1997) (“[T]here are three distinct claims for strict products liability” in New York: manufacturing defect, design defect, warning defect). Plaintiff cannot overcome federal preemption on any of these theories.

With respect to the design and manufacturing defect theories, she alleges nothing more than that the MRI Kit “failed to meet design-control and manufacturing requirements to ensure that [the device] conformed to defined use, needs, intended purpose and uses.” (Compl. ¶ 45). She does not allege what “requirements” the device purportedly failed to meet or explain how the device was defectively designed or manufactured in violation of those requirements, let alone specify whether or how the violation of any specific requirement caused her alleged injury. She “does not claim that the design of the [CI522 Device or the MRI Kit] deviated in any way from the design approved by the FDA, . . . [so her] design defect claim boils down to a direct attack on the very design approved by the FDA.” *Cordova*, 2014 WL 3749421, at *6; *see also Tansey v. Cochlear Ltd.*, 2014 WL 4829453, at *11 (“Plaintiff’s design defects claims are preempted under § 360k because such claims challenge the PMA approval of the design for the CI512 [a predecessor to the CI522].”).

Likewise, she fails to provide “specific allegations explaining how defendants’ manufacturing process was in violation of federal requirements [and thus] was defective.” *Horowitz*, 613 F. Supp. 2d at 283-84 (dismissing manufacturing defect claim as

preempted). Courts routinely have dismissed similarly vague claims as preempted. *See Burkett*, 2014 WL 1315315, at *4-5 (dismissing as preempted design and manufacturing defect claim for failure to state any deviation from approved design or identify a manufacturing defect specific to the device at issue); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) (dismissing as preempted design defect claims regarding PMA-approved device for failure to identify design flaw).

With respect to the failure-to-warn theory, Plaintiff merely alleges that “the MRI Kit failed to be accompanied by proper and sufficient instructions, directions and/or warnings concerning the use, the dangers and hazards attendant thereto; one or more of which were substantial factor [sic] or a proximate cause of the aforesaid injuries to the Plaintiff.” (Compl. ¶ 46). These wholly conclusory allegations are insufficient to escape preemption. *See Cordova*, 2014 WL 3749421, at *7 (dismissing failure to warn claim as preempted because plaintiff did “not base her claim upon the violation of any federal requirement”). “The FDA’s PMA approval includes specific language for Class III device labels and warnings.” *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010). Plaintiff “does not claim that [Defendants] modified or failed to include the labels and warnings that the FDA approved as part of the premarket approval process. Nor does [she] allege that [Defendants’] alleged failure to warn violated any other federal requirement.” *Cordova*, 2014 WL 3749421, at *6 (quotations omitted); *see also Burkett*, 2014 WL 1315315, at *6 (dismissing strict liability failure to warn claim as preempted because plaintiff “does not sufficiently reference federal requirements or regulations related to adequate warnings, let alone specific to the [product, nor does she] link the purported violation to her injury.”).

In sum, because Plaintiff does not identify any violation of any federal requirement, let

alone explain how that violation specifically caused or contributed to her injury, her strict liability claims are preempted and must be dismissed. As one court in this district recently explained in dismissing similarly-pled strict liability claims:

Not only does plaintiff fail to identify any specific design flaw in the subject contact lenses, but, more importantly for preemption purposes, she does not claim that the design as implemented deviated in any way “from the design approved by the FDA.” In similar fashion, [plaintiff] again fails to allege a violation of the federal manufacturing requirements specific to the contact lenses she claims injured her. Moreover, she does not even claim, let alone plausibly state facts to show, any link between her injuries and a defect resulting from a manufacturing defect, improper workmanship or defective materials in the production and sale of a product that, resultingly, did not comply with FDA regulations. As for the last straw, all of the promotional materials that [plaintiff] could have relied on were pre-approved by the FDA. Plaintiff does not plausibly plead facts supporting a claim that [defendant] modified or failed to include these labels and warnings that the FDA approved. Indeed, she does not even advance such a claim. Accordingly, none of these causes of action can survive preemption.

Crissi, 2016 WL 4502038, at *3 (internal quotations and citations omitted).

2) Plaintiff’s Negligence Claims Are Preempted

Plaintiff’s negligence claims fare no better. Plaintiff in her second cause of action alleges that Defendants “negligently designed and/or manufactured” the MRI Kit. (Compl. ¶¶ 54-57). And, in her fourth cause of action, she claims that Defendants had a duty to warn her medical providers of the risks and dangers associated with the use of the MRI Kit and failed to do so. (Compl. ¶¶ 66-68). Courts in this district, however, have consistently held that the MDA preempts negligence claims to the extent they rely on a design defect, manufacturing defect or failure to warn. *See, e.g., Franzese*, 2014 WL 2863087, at *7 (dismissing as preempted plaintiff’s negligence claim that defendant “failed to exercise reasonable care in the design, testing, manufacture, packaging, labeling, warnings, quality assurance, marketing, p[o]st-market monitoring and/or surveillance, advertising, promotion, distribution and sale of the Plaintiff’s [device]”); *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 258 (E.D.N.Y. 2014)

(“*Bertini II*”) (dismissing negligence claims based on design defect because they “would impose additional safety requirements on defendant’s device beyond what is required by federal regulations”). Such claims would require a jury “to find that the FDA requirements themselves were deficient,” which “would directly interfere with the PMA process.” *Horowitz*, 613 F. Supp. 2d at 283 (“Negligence claims must be considered preempted to the extent that they allege that the manufacturer was negligent despite its adherence to the standards required by the FDA in its PMA for this specific product.”) (internal quotations and alterations omitted). Plaintiff does not and cannot plead that Defendants violated any terms of the PMA regarding the design or manufacture of the MRI Kit or its associated warnings, or that any such purported violations caused her injuries. *See id.* at 282. Her claims are preempted and must be dismissed.

3) Plaintiff’s Breach of Warranty Claims Are Preempted

Plaintiff’s warranty claims also fail on preemption grounds for the same reasons. Her express warranty claim is based on a purported representation that patients can safely undergo an MRI procedure at 1.5 Tesla with the CI522 Device implant magnet in place. (Compl. ¶ 24-25). In other words, she takes issue with a purported statement that the CI522 Device, when used with the MRI Kit, is safe and effective – a representation that does nothing more than restate the conclusion made by the FDA when it approved the PMA supplement for the MRI Kit. The law is clear that express warranty claims based on FDA-approved representations as to safety and efficacy are preempted. *See Burkett*, 2014 WL 1315315, at *8 (citing *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 205–06 (W.D.N.Y. 2011); *Horowitz*, 613 F. Supp. 2d at 285.

With respect to Plaintiff’s conclusory claim for breach of implied warranty, she has not alleged that a violation of federal requirements caused the CI522 Device or the MRI Kit to be

unmerchantable or unfit for its intended purpose. Thus, “[f]or plaintiff to succeed on her claim, a jury would have to find that defendants breached the implied warranty of merchantability by manufacturing a medical device that was unsafe in its federally approved design or manufacture.” *Horowitz*, 613 F. Supp. 2d at 284. “Such a claim falls squarely within the MDA’s preemption provision.” *Id.*; see also *Burkett*, 2014 WL 1315315, at *8; *Franzese*, 2014 WL 2863087, at *7 (“[U]nder the MDA, plaintiffs cannot demand that defendant design the [medical device] in a safer manner, when the FDA has already approved the safety and effectiveness of defendant’s design.”) (internal quotations omitted).

4) *The MRI Kit Is, as a Matter of Law, a Class III Device*

Plaintiff concedes that the CI522 device is a PMA-approved Class III device. (ECF No. 13 at 1). However, she has argued in pre-motion filings in an effort to escape preemption that the CI522 Device and the MRI Kit are “separate products,” and that the MRI Kit is a Class II device under the MDA and did not require or receive PMA approval. That argument is incorrect – the MRI Kit is, as a matter of law, a Class III device. Plaintiff’s theory has shifted over time – initially she argued that the MRI Kit was a Class II device approved pursuant to the less rigorous 510(k) process. (ECF No. 9 at 2). That theory was easily disproven, as the MRI Kit does not appear in the FDA’s database of 510(k) premarket notification clearances for Class II devices, as would be the case if it had been cleared as a free-standing Class II device.¹⁴

Next, Plaintiff posited that the MRI Kit was exempted entirely from FDA approval (ECF No. 13 at 1-2), citing a 2017 FDA regulation that exempts certain Class II “MRI disposable kits” from 501(k) approval. But that regulation, which was promulgated a year *after* the FDA

¹⁴ See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>. There is no 510(k) application for the MRI Kit, because it was approved through the FDA’s rigorous PMA process, not the less stringent 510(k) clearance process.

approved the MRI Kit pursuant to the PMA Supplement, does ***not*** apply to CAM’s MRI Kit. The regulation cited by Plaintiff only applies to “convenience kits” comprised of existing, approved Class I or Class II devices intended for a generic purpose.¹⁵ Specifically, 21 C.F.R. § 892.1000 designates a “magnetic resonance imaging disposable kit intended for use with a magnetic resonance diagnostic device” as a Class II device that is “exempt from the premarket notification procedures … subject to the limitations in § 892.9.” Section 892.9, in turn, makes clear that the exemption applies to “a generic type of Class I or II device . . . only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type,” and where it is not “intended for a use different from the intended use of a legally marketed device in that generic type.” The Complaint itself makes clear that the MRI Kit is ***not*** a “generic type” of kit intended for a generic use – it was “specifically designed and sold by Defendants to protect [Cochlear] implant recipients . . . from the dangers associated with undergoing an MRI procedure with the Magnet in place.” (Compl. ¶ 22; *see also* Ex. A). Plaintiff is grasping at straws by attempting to conflate CAM’s MRI Kit – designed and approved for the specific and exclusive purpose of securing a Cochlear implant magnet during an MRI – with generic “convenience kits” used for MRI procedures generally simply because they have a similar name.¹⁶

¹⁵ The regulation is based on a 1997 FDA guidance document entitled “Convenience Kits Interim Regulatory Guidance,” which makes clear that the exemption only applies to “generic types of kits” “comprised of legally marketed devices that are simply being assembled in kit form strictly for the ‘convenience’ of the purchaser or user” and “that do[] not modify the intended use(s) of the individual kit components.” See FDA, Convenience Kits Interim Regulatory Guidance, (May 20, 1997), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/convenience-kits-interim-regulatory-guidance>.

¹⁶ The regulation itself makes clear that a manufacturer submitting a premarket notification under the exemption “cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices.” 21 C.F.R. § 892.1(b).

Even if the FDA’s approval of the 2016 PMA Supplement did not make clear that the MRI Kit was approved pursuant to the PMA process (it did), the law is clear that an “accessory” to a PMA-approved Class III device is itself a Class III device for purposes of preemption. The MDA defines “device” as “an instrument . . . or other similar or related article, *including any component, part, or accessory.*” 21 U.S.C. § 321(h) (emphasis added). Courts throughout the country have held that “components” of PMA-approved Class III devices are themselves Class III devices, even when sold separately or used with other non-Class III devices. As one such court recently explained:

To begin with, it is clear that breaking down a PMA-approved medical device into its components for the purpose of evaluating the reach of the MDA’s express preemption clause, as Plaintiffs suggest, runs afoul of the statutory definition of “device” under the MDA. That is, per the statute, a medical “device” includes “any component, part, or accessory[,]” 21 U.S.C. § 321(h), and in the context of the Paradigm Infusion System, there is no question that the MMT–522 Pump is precisely such a component part. Thus, the MMT–522 Pump falls within the scope of the device-related PMA approval that Medtronic received.

Kubicki v. Medtronic, Inc., 293 F. Supp. 3d 129, 175 (D.D.C. 2018) (alterations in original).¹⁷ The same reasoning applies to accessories – separating the CI522 Device from the MRI Kit upon which the FDA’s approval of the PMA supplement was based would “run[] afoul of the statutory definition of ‘device’ under the MDA.” *Id.*; *see also*

¹⁷ See also *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1003 (S.D. Ohio 2016) (“Premarket approval extends to all components of an approved device, even when a physician uses the components separately.”); *Hawkins v. Medtronic*, No. 1:13-cv-0499 AWI SKO, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) (“The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself.”); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 488 (W.D. Pa. 2012) (“Despite the prior § 510(k) approval of the metal acetabular cup and its commercial availability at the time of the Trident System’s premarket approval, the metal acetabular cup still underwent the PMA process as a component of the Trident System.”); *Bentley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 450–51 (E.D. Pa. 2011) (rejecting plaintiff’s “attempts to raise an issue of material fact by arguing that the MMT–522 pump is ‘separate and apart from the insulin infusion system and did not gain approval through the PMA process.’”).

21 C.F.R. § 814.80 (“A device may not be . . . distributed . . . in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.”); *Troutman v. Curtis*, 143 P.3d 74, 78, 85 (Kan. Ct. App. 2006), *aff’d* 185 P.3d 930 (Kan. 2008) (noting that a “new accessory device” used with a Class III suture closing device was approved pursuant to a supplement to the original device’s PMA, and that “[h]ad the conditions of approval not been met, [defendant] would not have been allowed to distribute the [device] and its accessories”). Both the CI522 Device – and its accessory the MRI Kit – together are a Class III “device,” and Plaintiff’s failure to plead the violation of a specific federal requirement applicable to that device warrants dismissal of her claims. *See, e.g.*, *Crissi*, 2016 WL 4502038, at *2.

B. Plaintiff’s Claims are Inadequately Pled

Even if Plaintiff’s claims were not expressly preempted by the MDA, the Complaint falls far short of the basic federal pleading requirements articulated in *Iqbal* and *Twombly*. Plaintiff alleges that her implant magnet became dislodged during an MRI. (Compl. ¶ 32). While she initially attributed her injury to negligence by her healthcare providers (*see* Exhibits C-D), she now seeks to blame it on some unidentified defect or failure by Defendants. The Complaint is silent, however, as to what, precisely, Defendants have done wrong. Instead, Plaintiff does nothing more than recite the elements of a laundry list of claims. Such vague, “the-defendant-unlawfully-harmed-me” allegations fail to pass muster under federal pleading standards. *Iqbal*, 556 U.S. at 678.

1) *Strict Liability*

Plaintiff’s strict liability cause of action for design, manufacturing and warnings defect fails to state a claim. “A design defect claim is subject to dismissal where plaintiff fails to plead

facts identifying how the device is defectively designed or the existence of a feasible alternative design.” *Bertini v. Smith & Nephew, Inc.*, No. 13 CIV. 0079(BMC), 2013 WL 6332684, at *3-4 (E.D.N.Y. July 15, 2013) (“*Bertini I*”) (dismissing design defect claim against medical device manufacturer); *see also Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577-78 (E.D.N.Y. 2012) (dismissing design defect claim against prescription drug manufacturer). Plaintiff fails to do so here. Instead, she “merely plead[s] the legal conclusion that the [product] was defective.” *Reed*, 839 F. Supp. 2d at 577-78; *see also Surdo v. Stamina Prod., Inc.*, No. 15-CV-2532, 2015 WL 5918318, at *4 (E.D.N.Y. Oct. 9, 2015) (noting that conclusory allegations that a product is “inherently dangerous” or “defective” are insufficient). She alleges nothing more than that “the MRI Kit was not reasonably safe” and that “it failed to meet design-control . . . requirements to ensure that the device conform [sic] to defined use, needs, intended purposes and uses.” (Compl. ¶¶ 43, 45). But “the mere fact that the device did not perform as intended is not by itself indicative of a flaw in the . . . design processes.” *Bertini I*, 2013 WL 6332684, at *3. Nor does Plaintiff even attempt to “plead facts alleging the existence of a feasible alternative design that would make the product safer” *Goldin v. Smith & Nephew, Inc.*, No. 12 Civ. 9217(JPO), 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24, 2013); *see also Surdo*, 2015 WL 5918318, at *4 (“[A] design defect claim is properly dismissed where a plaintiff fails to plead facts alleging the existence of a feasible design alternative.”); *Reed*, 839 F. Supp. 2d at 578 (dismissing design defect claim for failure to plead a feasible alternative design).

Likewise, Plaintiff’s manufacturing defect claim is subject to dismissal because she does not put forth any facts alleging how her MRI Kit deviated from its intended design. *See Bertini I*, 2013 WL 6332684, at *3 (“[A] manufacturing defect claim is properly dismissed if a plaintiff has not alleged that the device in his case had a defect as compared to other samples of that

device.”) (internal quotations and alterations omitted); *Reed*, 839 F. Supp. 2d at 577 (same). She merely states, in conclusory fashion, that the MRI Kit “failed to meet . . . manufacturing requirements.” (Compl. ¶ 45). “[T]hat does not allege an error in the manufacturing process – it only states that there was one.” *Surdo*, 2015 WL 5918318, at *5 (dismissing manufacturing defect claim against device manufacturer). Absent more detailed facts, Plaintiff has “not nudged [her] claim[] across the line from conceivable to plausible,” *see Twombly*, 550 U.S. at 570, and has failed to state a claim for manufacturing defect under New York law.

Finally, Plaintiff’s failure to warn claim fails because she does not identify any specific warnings or how those warnings were inadequate. *See Bertini I*, 2013 WL 6332684, at *3-4. To state a strict-liability claim for failure to warn, a plaintiff must “demonstrate that (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm.” *Franzese*, 2014 WL 2863087, at *6 (quoting *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App’x 8, 10 (2d Cir. 2011)). “It follows that ‘a failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate.’” *Surdo*, 2015 WL 5918318, at *5 (quoting *Reed*, 839 F. Supp. 2d at 575). Here, the Complaint merely states that “the MRI Kit failed to be accompanied by proper and sufficient instructions, directions and/or warnings concerning the use, the dangers and hazards attendant thereto; one or more of which were substantial factor or a proximate cause of the aforesaid injuries to the Plaintiff.” (Compl. ¶ 46). Plaintiff “does not plead that the defendants had a duty to warn; [s]he does not specify the danger [s]he was not warned about; and [s]he does not describe how the failure to warn resulted in [her] injuries. Furthermore, [s]he fails to plead

facts stating how the provided warnings were inadequate, further warranting dismissal of the claim.” *Surdo*, 2015 WL 5918318, at *5.

2) Negligence

Plaintiff also fails to state a claim for negligence – either with respect to her claim for negligent design/manufacture in the second cause of action or her claim for negligent failure to warn in the fourth cause of action. To state a claim for negligence, a plaintiff must show “(1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, *i.e.* reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff’s injury; and (4) loss or damage.” *Franzese*, 2014 WL 2863087, at *8 (internal quotations omitted). Other than conclusory statements, the Complaint is devoid of allegations supporting any of these elements.

Plaintiff’s second cause of action alleges only that Defendants “negligently designed and/or manufactured” the MRI Kit. (Compl. ¶¶ 54-57). As the *Bertini I* court noted in dismissing similar conclusory negligence claims, [t]hese are boilerplate allegations from some form book. Plaintiff[] fail[s] to support them with any specific facts.” *Bertini I*, 2013 WL 6332684, at *5; *see also In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484-85 (E.D.N.Y. 2012) (dismissing negligence claim where plaintiff alleged that defendants “failed to exercise reasonable care in testing, manufacturing, labeling, marketing, distributing and selling” their drug, because these were merely conclusory allegations with no factual support).

Plaintiff’s fourth cause of action – alleging negligent failure to warn – fares no better. Plaintiff alleges nothing more than that “Defendants failed to warn Plaintiff’s medical care providers of the risks and dangers associated with the use of the MRI Kit in the manner in which it was intended to be used or in a reasonably foreseeable manner of use.” (Compl. ¶ 68). This

boilerplate recitation provides no *facts* as to what risk Defendants purportedly failed to warn about, how any specific warnings were inadequate or how any specific failure to warn caused Plaintiff's alleged injuries. *See, e.g., Surdo*, 2015 WL 5918318, at *5.

3) *Breach of Warranty*

To state a claim for breach of express warranty, a plaintiff must identify an “affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain,” and also allege that she relied on that representation in purchasing the product. *See Horowitz*, 613 F. Supp. 2d at 286 (quoting N.Y. U.C.C. § 2-313(1)(a)); *Surdo*, 2015 WL 5918318, at *6. The Complaint generically alleges that “Defendants warranted that Plaintiff could safely undergo an MRI procedure with her Magnet in place under skin provided that the MRI Kit was used,” (Compl. ¶ 61), and further states in conclusory fashion that “[p]rior to February 14, 2018, Defendants represented to Plaintiff and/or to her physicians that the MRI procedure could be safely performed upon Plaintiff, with the [CI522 Device] in situ, without removal of the Magnet, provided the MRI Kit was first applied to Plaintiff in the manner directed by Defendants” and that “Defendants specifically represented to Plaintiff and/or her physicians that Plaintiff ‘can be safely scanned’ using ‘the MRI Kit for MR scans at 1.5 T[esla] with the implant magnet in place.’” (Compl. ¶¶ 24-25). But these purported “representations,” which paraphrase the FDA’s approval of the 2016 PMA Supplement, “are insufficient to sustain [Plaintiff’s] claim because [s]he fails to describe how this representation was made or how [s]he relied on it.” *Surdo*, 2015 WL 5918318, at *6. As the court noted in dismissing a similar breach of warranty claim in *Horowitz*, “[n]owhere in her amended complaint does plaintiff allege that she relied on defendants’ alleged representation that the [product] was ‘safe.’ Plaintiff does not even describe how this representation was made.” *Horowitz*, 613 F. Supp. 2d at 286 ; *see also*

Burkett, 2014 WL 1315315, at *8 (dismissing express warranty claim where plaintiff alleged vague representations of safety and efficacy in “advertising and promotional materials,” but did not identify any specific materials); *Goldin*, 2013 WL 1759575, at *6. Here, Plaintiff cannot even say whether the purported representations were made to her or her physicians. And, she does not allege, even in conclusory fashion, that the purported representations had any impact on her decision to undergo an MRI procedure using the MRI Kit.

To state a claim for breach of the implied warranty of merchantability,¹⁸ “a plaintiff must show that the product was not reasonably fit for its intended purpose, an inquiry that focuses on the expectations for the performance of the product when used in the customary, usual[,] and reasonably foreseeable manners.” *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 420–21 (S.D.N.Y. 2011) (internal quotations omitted). Plaintiff has not pled any facts to support such a claim. The mere fact that Plaintiff was injured is “insufficient to establish that the [MRI Kit] was not minimally safe for its intended purposes when it was shipped.” *Dellatacoma v. Polychem Corp.*, No. 12 CIV. 7916 (LTS), 2014 WL 1641467, at *2 (S.D.N.Y. Apr. 24, 2014) (dismissing implied warranty claim). Her breach of warranty claim should be dismissed. See *Reed*, 839 F. Supp. 2d at 579-80; *Surdo*, 2015 WL 5918318, at *6.

CONCLUSION

For the foregoing reasons, CAM’s Motion should be granted in its entirety. Moreover, because any further amendment would be futile, this case should be dismissed with prejudice.

¹⁸ Plaintiff does not allege any of the elements of a claim for breach of implied warranty of fitness for a particular purpose, namely that Defendants (1) had reason to know at the time of contracting a particular purpose for which the MRI Kit was required; (2) that the Plaintiff was justifiably relying upon Defendants’ skill and judgment to select and furnish a suitable device; or (3) that Plaintiff actually relied on that skill. See *Blue Ridge Farms, Inc. v. Crown Equip. Corp.*, No. 01 CV 8460SJ, 2005 WL 755756, at *15 n.7 (E.D.N.Y. Mar. 31, 2005); see also *Catalano v. BMW of N. Am., LLC*, 167 F. Supp. 3d 540, 558 (S.D.N.Y. 2016) (dismissing claim where the manufacturer was not alleged to have engaged directly with the buyer).

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Baltimore, Maryland

Respectfully submitted,

HOGAN LOVELLS US LLP

By:/s/ Lauren S. Colton

Lauren S. Colton (*pro hac vice*)
100 International Drive, Suite 2000
Baltimore, MD 21202
Tel.: (410) 659-2700
Fax: (410) 659-2701
lauren.colton@hoganlovells.com

David J. Barron
390 Madison Avenue
New York, New York 10017
Tel: (212) 918-3000
Fax: (212) 918-3100
david.barron@hoganlovells.com

Attorneys for Defendant Cochlear Americas Corporation